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10/713,530	11/13/2003	Andrew Thomas Forsberg	47563.0014	9304

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EXAMINER	
COLELLO, ERIN L	

ART UNIT	PAPER NUMBER
3734	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/713,530	FORSBERG ET AL.	
	Examiner	Art Unit	
	ERIN COLELLO	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 June 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,7,12-16,21,22,24,25,28,33-38,45-49,52-54 and 57-60* is/are pending in the application.

4a) Of the above claim(s) *4,7,12,22,24,25 and 33-38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 13-16, 21, 28, 45-49, 52-54 and 57-60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to the Request for Continued Examination filed on June 23, 2010. Claims 5, 20, 39 and 51 have been cancelled without prejudice. Claims 1, 4, 7, 12-16, 21-22, 24-25, 28, 33-38, 45-49, 52-54, 57-60 are currently pending with claims 4, 7, 12, 22, 24-25 and 33-38 withdrawn from consideration as being drawn to a non-elected species.

Applicant's arguments filed June 23, 2010 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 45 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claim 45 recites the limitation "the third indicator" in lines 16 and 21 of claim 45. There is insufficient antecedent basis for this limitation in the claim.

Claim Objections

4. Claim 45 is objected to because of the following informalities: line 10 states "wherein the third distal hold". Appropriate correction is required.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

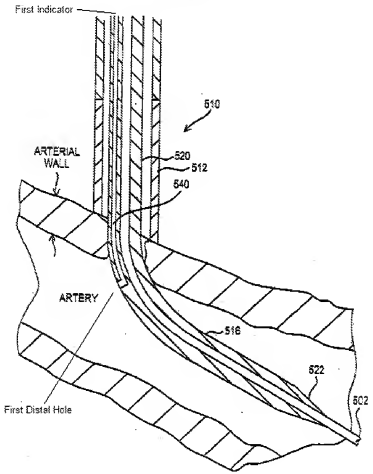
2. Claims **1, 14-16, 28, 45-49, 52-54 and 57-59,** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Kanner et al. (US 6,767,356 B2).**

Regarding claims 1, 45, 47, 52, 57, 58 and 59, Kanner discloses a vascular insertion assembly, comprising: an insertion sheath having a distal end and a proximate end (Ref 512); a dilator having a distal end and a proximate end sized to fit inside the insertion sheath (Ref 520), the dilator having a distal end positionable distally beyond a distal end of the insertion sheath (Ref 516); a first distal hole located in the distal end of the dilator such that the first distal hole is positionable distally beyond the distal end of the insertion sheath, the first distal hole being open for fluid flow only after being positioned distally beyond the distal end of the insertion sheath; wherein the first distal hole is a first inlet port (Figure 20A see below; Figures 38, 39); a first indicator located at a proximal end of the dilator (Column 8, Lines 37-50; wherein the proximal end of the blood marking lumen is a first indicator that indicates the position of the insertion assembly to the user), the first indicator being in fluid communication with the first distal hole so that when the first distal hole (inlet port) penetrates a vessel, the first indicator (outlet port) at the proximal end indicated an initial penetration of the vascular insertion assembly into the vessel (Ref 540; wherein a lumen in the dilator provides the fluid

communication that indicates to the user the depth; Column 8, Lines 37-50); a second distal hole located in the distal end of the insertion sheath (Column 8, lines 37-59; wherein the assembly can contain an additional passageway which would be similar to the first passageway and would include a distal hole similar to the one shown in Figure 20A below); the second distal hole being offset longitudinally in a proximal direction (Column 8, Lines 37-59; wherein the additional passageway is proximal to the first passage in order to indicate that the depth of the assembly is too far); wherein the second distal hole is a second inlet port also known as an over insertion hole (Column 8, Lines 37-59; Column 18, Lines 60-67; Column19, Lines 1-31); and a second indicator located at a proximal end of the insertion sheath; wherein the second indicator is a second proximal hole also known as an outlet port of an over insertion indicator (Column 8, lines 37-59; wherein the assembly can contain an additional passageway which would be similar to the first passageway and would include an indicator similar to the one shown in Figure 20A below; wherein the additional passageway can be in the dilator or the sheath) the second indicator being in fluid communication with the second distal hole so that when the second distal hole (inlet port) penetrates the vessel, fluid flows out of the second indicator at the proximal end and indicates that the vascular insertion assembly is at another depth in the vessel; wherein the second depth represents an over insertion of the vascular insertion assembly into the vessel (Column 8, Lines 37-60; Column 18, Lines 55-67; Column 19, Lines 1-31; wherein the additional passageway can be in the dilator or the sheath and would be similar to the first

passageway connecting a distal hole and an indicator in order to indicate that the depth of the assembly is too far)

FIG. 20A



Kanner discloses all of the claimed limitations above but fails to explicitly disclose that the proximal end of the blood marking lumen is a hole or outlet port; where fluid can flow out.

However, in an alternate embodiment, Kanner teaches that the proximal end of a blood marking lumen in the sheath comprises a port for observing the presence of blood

due to the proximal end entering a vessel (Column 18, Lines 55-65; Column 19, Lines 1-31).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the proximal end of the first blood marking lumen to include a hole or port as taught by Kanner in Figures 33 and 34, since such a modification provides an easy way for the user to observe the presence of blood and determine the position of the insertion instrument.

Kanner fails to explicitly disclose that the first distal hole and the second distal hole can be circumferentially spaced.

However, in an alternate embodiment, Kanner teaches that it is well known in the art to include a first passageway and a second passageway; wherein each passageway includes a distal hole and a proximal hole; wherein the first distal hole is circumferentially spaced from the second hole (Figures 33 and 34, (674), (675)).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the first and second passageways and therefore the first and second distal holes of Kanner to be circumferentially spaced from one another, since such a modification enhances the device by allowing the insertion of the device to be monitored at different locations.

Kanner fails to explicitly disclose an additional distal hole (third) located at the distal end of the vascular insertion assembly or an additional indicator (third) located at the proximal end of the vascular insertion assembly; wherein the additional distal hole (third) and the additional distal indicator (third) are in fluid communication with one

another and wherein the first, second and the additional distal hole are spaced apart from each other in a lengthwise direction.

However, in an alternate embodiment, Kanner teaches that it is well known in the art and therefore would have been obvious to include additional blood marking lumens in the sheath or dilator to any other introducer embodiments in order to identify the insertion depth of a transluminal device; wherein the device can a third distal hole that is located at the distal end of the vascular insertion assembly (Ref 674 or 675) and a third indicator is located at the proximal end of the vascular insertion assembly (Ref 684 or 688), wherein the third distal hole is in fluid communication with the third indicator (Ref 689 A and B; Column 8, Lines 37-60; Column 18, Lines 55-67); wherein the third distal hole can be offset longitudinally (Compare Figures 33 and 34, Ref 674 and 675), such that the additional (third) outlet port can indicate proper insertion of the vascular insertion assembly into the vessel (Column 18, lines 55-67; Column 19, lines 1-31; wherein the presence of blood flow at 684 and not at 688 indicates that the distal end of the guide sheath is sufficiently inserted into the site).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device to include a plurality of distal holes located at the distal end of the vascular insertion assembly and a plurality of proximal indicators located at the proximal end of the vascular insertion assembly, as taught by Kanner, since such a modification allows the insertion depth of a transluminal device to be identified and ensures that the device is sufficiently inserted into the site.

Regarding claims 28, 46, 48-49, 53 and 54, Kanner discloses a vascular insertion assembly, comprising: an insertion sheath having a distal end and a proximate end (Ref 512); a dilator having a distal end and a proximate end sized to fit inside the insertion sheath (Ref 520), the dilator having a distal end positionable distally beyond a distal end of the insertion sheath (Ref 516); a first distal hole located in the distal end of the dilator such that the first distal hole is positionable distally beyond the distal end of the insertion sheath, the first distal hole being open for fluid flow only after being positioned distally beyond the distal end of the insertion sheath; wherein the first distal hole is a first inlet port (Figure 20A see below; Figures 38, 39); a first indicator located at a proximal end of the dilator (Column 8, Lines 37-50; wherein the proximal end of the blood marking lumen is a first indicator that indicates the position of the insertion assembly to the user), the first indicator being in fluid communication with the first distal hole so that when the first distal hole (inlet port) penetrates a vessel, the first indicator (outlet port) at the proximal end indicated an initial penetration of the vascular insertion assembly into the vessel at a first depth (Ref 540; wherein a lumen in the dilator provides the fluid communication that indicates to the user the depth; Column 8, Lines 37-50); a second distal hole located in the distal end of the insertion sheath (Column 8, lines 37-59; wherein the assembly can contain an additional passageway which would be similar to the first passageway and would include a distal hole similar to the one shown in Figure 20A above); the second distal hole being offset longitudinally from the first distal hole (Column 8, Lines 37-59; wherein the additional passageway is proximal to the first passage in order to indicate that the depth of the assembly is too far);

wherein the second distal hole is a second inlet port also known as an over insertion hole (Column 8, Lines 37-59; Column 18, Lines 60-67; Column19, Lines 1-31); and a second indicator located at a proximal end of the insertion sheath; wherein the second indicator is a second proximal hole also known as an outlet port of an over insertion indicator (Column 8, lines 37-59; wherein the assembly can contain an additional passageway which would be similar to the first passageway and would include an indicator similar to the one shown in Figure 20A above; wherein the additional passageway can be in the dilator or the sheath), the second indicator being in fluid communication with the second distal hole via a flow path defined by the insertion sheath, the flow path being positioned radially inward of an outer surface of the insertion sheath so that when the second distal hole (inlet port) penetrates the vessel, fluid flows out of the second indicator at the proximal end and indicates that the vascular insertion assembly is at another depth in the vessel; wherein the second depth represents an over insertion of the vascular insertion assembly into the vessel (Column 8, Lines 37-60; Column 18, Lines 55-67; Column 19, Lines 1-31; wherein the additional passageway can be in the dilator or the sheath; and would be similar to the first passageway connecting a distal hole and an indicator in order to indicate that the depth of the assembly is too far; wherein the first passageway is positioned radially inward of the outer surface).

Kanner discloses all of the claimed limitations above but fails to explicitly disclose that the proximal end of the blood marking lumen is a hole or outlet port; where fluid can flow out.

However, in an alternate embodiment, Kanner teaches that the proximal end of a blood marking lumen in the sheath comprises a port for observing the presence of blood due to the proximal end entering a vessel (Column 18, Lines 55-65; Column 19, Lines 1-31).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the proximal end of the first blood marking lumen to include a hole or port as taught by Kanner in Figures 33 and 34, since such a modification provides an easy way for the user to observe the presence of blood and determine the position of the insertion instrument.

Kanner fails to explicitly disclose an additional distal hole (third) located at the distal end of the vascular insertion assembly or an additional indicator (third) located at the proximal end of the vascular insertion assembly; wherein the additional distal hole (third) and the additional distal indicator (third) are in fluid communication with one another and wherein the first, second and the additional distal hole are spaced apart from each other in a lengthwise direction.

However, in an alternate embodiment, Kanner teaches that it is well known in the art and therefore would have been obvious to include additional blood marking lumens in the sheath or dilator to any other introducer embodiments in order to identify the insertion depth of a transluminal device; wherein the device can a third distal hole that is located at the distal end of the vascular insertion assembly (Ref 674 or 675) and a third indicator is located at the proximal end of the vascular insertion assembly (Ref 684 or 688), wherein the third distal hole is in fluid communication with the third indicator (Ref

689 A and B; Column 8, Lines 37-60; Column 18, Lines 55-67); wherein the third distal hole can be offset longitudinally (Compare Figures 33 and 34, Ref 674 and 675), such that the additional (third) outlet port can indicate proper insertion of the vascular insertion assembly into the vessel (Column 18, lines 55-67; Column 19, lines 1-31; wherein the presence of blood flow at 684 and not at 688 indicates that the distal end of the guide sheath is sufficiently inserted into the site).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device to include a plurality of distal holes located at the distal end of the vascular insertion assembly and a plurality of proximal indicators located at the proximal end of the vascular insertion assembly, as taught by Kanner, since such a modification allows the insertion depth of a transluminal device to be identified and ensures that the device is sufficiently inserted into the site.

Regarding claim 14, Kanner discloses a first lumen that provides the fluid communication between the first distal hole and the first indicator; wherein the first lumen passes through the dilator (Ref 540; 520).

Regarding claims 15 and 16, Kanner discloses a second lumen that provides the fluid communication between the second distal hole and the second indicator; wherein the second lumen passes through the dilator (Column 8, Lines 37-60; Column 18, Lines 55-67; Column 19, Lines 1-31; wherein the additional passageway can be in the dilator or the sheath and would be similar to the first passageway connecting a distal hole and an indicator in order to indicate that the depth of the assembly is too far)

3. Claims 13, 21 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Kanner et al. (US 6,767,356 B2)** in view of **Ginn et al. (US 6,626,918 B1).**

Regarding claim 13, Kanner discloses all of the claims above including a first indicator and a second indicator but fails to explicitly disclose that at least one of the first indicator or the second indicator is a hole defined in the sidewall of at least one of the dilator and insertion sheath.

However, Ginn teaches that it is well known in the art for a vascular insertion assembly to include an indicator defined as a hole in the sidewall of an insertion sheath which can communicate with a flush port or other back-bleed indicator in order to flush blood or other visible body fluid from the proximal side port (Column 6, Lines 19-35 and 59-67; Column 7, lines 1-6).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify an indicator of Kanner to be a hole in the sidewall as taught by Ginn, since such a modification allows the port to be connected to a flush port which flushes blood or other visible body fluid from the proximal side port.

Regarding claim 21, Kanner discloses all of the claimed limitations above but fails to explicitly disclose a lumen having a first flow path and a second flow path; wherein the first flow path provides the fluid communication between the first distal hole and the first indicator; and the second flow path provides the fluid communication between the second distal hole and the second indicator.

However, Ginn teaches that it is well known in the art that vascular insertion assembly can include a lumen having a first flow path (Figure 17A, 651, 652, 653) and a

second flow path (Figure 17A, (650, 648, 644); wherein the first flow path provides the fluid communication between the first distal hole and the first indicator (Figure 17A, 651, 652, 653); and the second flow path provides the fluid communication between the second distal hole and the second indicator (Figure 17A, (650), (648), (644); wherein both the first flow path and the second flow path are within the central lumen of the sheath).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the vascular insertion assembly to have a lumen with first and second flow paths as taught by Ginn, since such a modification allows the interior instrument to rotate in order to allow some ports to be obstructed while allowing fluid to enter other ports.

Regarding claim 60, Kanner discloses all of the claimed limitations above including that the second inlet port and the second outlet port are in fluid communication by way of a lumen that passes through the insertion sheath but fails to explicitly disclose that that the first inlet port and the first outlet port can be in fluid communication by way of a lumen that passes through the insertion sheath.

However, Ginn teaches that it is well known in the art for indicators of a vascular insertion assembly to be in fluid communication by way of a lumen that passes through the insertion sheath (Figure 16A-B, (550), (648), (544)).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the first indicator and the first lumen to pass through the

insertion sheath as taught by Figures 16A-B of Ginn, since such a modification makes it easier to distinguish between the two visual indicators.

Furthermore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include two indicators and two lumens passing through the insertion sheath, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v Bemis Co.*, 193 USPQ 8.

Response to Arguments

Applicant's arguments filed January 6, 2010 have been fully considered but they are not persuasive.

- The Applicant argues that Kanner fails to explicitly disclose an additional (third) distal hole and indicator, since Kanner merely discloses that an additional (second) marking passageway can be included proximal to the first blood marking passageway.

The Examiner respectfully disagrees. As shown in the rejection above, Kanner discloses that an additional blood marking passageway can be included proximal to the first blood marking passageway and can be located in the dilator or the distal end of the sheath and will include internal passageways or lumens for blood marking (Column 8l, Lines 37-59; wherein a blood marking passageway includes a distal hole, a proximal hole and an internal flow path connecting the holes) and Kanner additionally teaches in an alternate embodiment that it would have been obvious to include additional blood marking lumens in the sheath or dilator to any other introducer embodiments in order to

identify the insertion depth of a transluminal device; wherein the device can a third distal hole that is located at the distal end of the vascular insertion assembly (Ref 674 or 675) and a third indicator is located at the proximal end of the vascular insertion assembly (Ref 684 or 688), wherein the third distal hole is in fluid communication with the third indicator (Ref 689 A and B; Column 8, Lines 37-60; Column 18, Lines 55-67); wherein the third distal hole can be offset longitudinally (Compare Figures 33 and 34, Ref 674 and 675), such that the additional (third) outlet port can indicate proper insertion of the vascular insertion assembly into the vessel (Column 18, lines 55-67; Column 19, lines 1-31; wherein the presence of blood flow at 684 and not at 688 indicates that the distal end of the guide sheath is sufficiently inserted into the site). Since Kanner teaches first, second and third distal and proximal holes in a vascular insertion assembly in order to identify the insertion depth of a transluminal device and ensures that the device is sufficiently inserted into the site, the arguments are not persuasive.

Conclusion

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIN COLELLO whose telephone number is (571)270-3212. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. C./
Examiner, Art Unit 3734

/TODD E. MANAHAN/

Supervisory Patent Examiner, Art Unit 3734